

REMARKS

Claims 22-50 are pending in the present application. Claims 22, 35 and 36 have been amended. Claims 49 and 50 have been presented herewith.

Telephone Interview

Applicants respectfully request Examiner Fritchman to contact the undersigned to conduct a telephone interview prior to finalizing examination.

Information Disclosure Statement

An Information Disclosure Statement has been filed on June 17, 2010. **The Examiner is respectfully requested to acknowledge receipt of the Information Disclosure Statement, and to confirm that the documents listed therein have been considered and will be cited of record in the present application.**

Claim Rejections-35 U.S.C. 102

Claims 22, 37 and 39-46 have been rejected under 35 U.S.C. 102(b) as being anticipated by the Berndtsson reference (U.S. Patent No. 6,387,328). This rejection, insofar as it may pertain to the presently pending claims, is traversed for the following reasons.

The cartridge of claim 22 includes in combination among other features a first liquid storage chamber "that has prestored therein a lysing reagent that lyses erythrocytes while maintaining counting ability of other blood cell types", and a first sampling member "being movably positioned in relation to the housing in such a way that in a first position, the first cavity is in communication with the bore to receive and hold the blood sample, and in a second position, the first liquid storage chamber communicates through the first cavity with the first mixing chamber so that the blood sample held in the first cavity can be flushed with the lysing reagent prestored in the first liquid storage chamber into the first mixing chamber and mixed with the lysing reagent in the first mixing chamber housing".

Prestoring a lysing reagent in the first liquid storage chamber of the cartridge provides a cartridge with few components and that is simple in operation and flow. In contrast, the cartridge of the Berndtsson reference has a complicated flow operation and requires a piston in order to move liquid from cylinder 44 (interpreted as first mixing chamber) to large volume space 61 (interpreted as first liquid storage chamber).

Further, Applicants respectfully submit that channel 63, capillary 64 and bleed recess 62 in Fig. 2 of the Berndtsson reference as taken together can not be interpreted as the first collection chamber of claim 22. By dictionary definition, and also in light of the description in the application, the plain meaning of a chamber should be recognized as "an enclosed space; cavity". In contrast, the plain meaning of a channel should be

recognized as "a tubular passage for liquids or fluids", and a capillary as "a tube with a small bore". (Copies of the dictionary definitions are attached.) Applicants respectfully submit that in view of plain meaning as would be understood by one of ordinary skill, channel 63 and/or capillary 64 in Fig. 2 of the Berndtsson reference should not be interpreted as a chamber. In view of plain meaning, claim 22 includes three chambers (the first liquid storage chamber, the first mixing chamber and the first collection chamber), while in contrast the structure in Fig. 2 of the Berndtsson reference includes only two chambers (large volume space 61 and cylinder 44). The Berndtsson reference thus fails to meet the features of claim 22 as asserted by the Examiner.

Further, the counting electrodes of the Berndtsson reference are disposed within channel 63 and not in chambers, as would be necessary to meet the features of claim 22. Positioning of electrodes within channel 63 in the Berndtsson reference makes counting less reliable.

Moreover, in the cartridge of the Berndtsson reference shown in Fig. 2, the sample does not reach bleed recess 62 in turning valve 50. As should be understood particularly with respect to Figs. 8 and 9 of the Berndtsson reference as described in column 5, lines 18-30, when the sample reaches detector 72 counting is stopped, and the valve body is then returned to the original position as shown in Fig. 9 so that bleed recess 62 is closed. The sample is not shown in bleed recess 62. Bleed recess 62 of the Berndtsson reference thus can not be interpreted as a first collection chamber, as would be necessary to meet the features of claim 22.

With further regard to this rejection, the Examiner has interpreted cylinder 44 in Fig. 2 of the Berndtsson reference as the first mixing chamber of claim 22. However, as described in column 4, lines 15-18 of the Berndtsson reference, diluting liquid L is stored in cylinder 44 when the device is manufactured. In the device shown in Fig. 2 of the Berndtsson reference, diluting liquid L is not prestored in large volume space 61 (interpreted as the first liquid storage chamber of claim 22), as would be necessary to meet the features of claim 22.

Applicants therefore respectfully submit that the cartridge of claim 22 distinguishes over the Berndtsson references as relied upon by the Examiner, and that this rejection, insofar as it may pertain to claims 22, 37 and 39-46, is improper for at least these reasons.

Claim Rejections-35 U.S.C. 103

Claims 23-36, 47 and 48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Berndtsson reference in view of the Mallinckrodt reference (European Patent Publication No. 1182457).

Applicants respectfully submit that the Mallinckrodt reference as secondarily relied upon by the Examiner does not overcome the above noted deficiencies of the primarily relied upon Berndtsson reference, and that this rejection, insofar as it may pertain to the presently pending claims, is improper for at least these reasons.

Claim 38 has been rejected under 35 U.S.C. 103(a) as being obvious over the

Berndtsson reference in view of the Seymour reference (U.S. Patent No. 5,393,496).

Applicants respectfully submit that the Seymour reference as secondarily relied upon by the Examiner does not overcome the above noted deficiencies of the primarily relied upon Berndtsson reference, and that this rejection, insofar as it may pertain to the presently pending claims, is improper for at least these reasons.

Claims 22, 37 and 39-46 have been rejected in the alternative under 35 U.S.C. 103(a) as being unpatentable over the Berndtsson reference in view of the Doutre reference (EP 0193394). This rejection, insofar as it may pertain to the presently pending claims, is traversed for the following reasons.

The Examiner has relied upon the Berndtsson reference in a somewhat similar manner, however interpreting capillary 64 and bleed recess 62 in Fig. 2 as the first collection chamber of claim 22. The Examiner has relied on the Doutre reference to show an aperture in a wall, with a pair of electrodes disposed on opposite sides of the wall.

Applicants respectfully submit that this rejection is improper for at least somewhat similar reasons as set forth previously with respect to claim 22. In particular, in view of the plain meaning as would be understood by one of ordinary skill, capillary 64 in Fig. 2 of the Berndtsson reference can not be interpreted as a chamber. Moreover, the sample does not reach bleed recess 62. Also, diluting liquid L is not prestored in large volume space 61, as would be necessary to meet the features of claim 22. The Doutre reference as secondarily relied upon does not overcome these

deficiencies of the primarily relied upon Berndtsson reference.

Applicants therefore respectfully submit that the cartridge of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection, insofar as it may pertain to claims 22, 37 and 39-46, is improper for at least these reasons.

Claims 23-36, 47 and 48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Berndtsson and Doutre references, in further view of the Mallinckrodt reference. Also, claim 38 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the Berndtsson and Doutre references, in further view of the Seymour reference. Applicants respectfully submit that the secondary references as respectively relied upon do not overcome the deficiencies of the primarily relied upon Berndtsson and Doutre references, and that these respective rejections are thus improper for at least these reasons.

Claims 49 and 50

Claim 49 includes in combination that the cartridge comprises a pressure channel "communicating with the first collection chamber, the pressure channel being adapted for coupling to a pressure source such that liquid flow through the first orifice is controlled by pressure applied by the pressure source". A cartridge with further simplified flow/operation and design is provided.

As noted above, the Examiner has interpreted capillary 64, bleed recess 62 and

channel 63 in Fig. 2 of the Berndtsson reference as the first collection chamber of the claims. However, capillary 64, bleed recess 62 and channel 63 in Fig. 2 of the Berndtsson reference are not disclosed or even remotely suggested as having a pressure channel in communication therewith, that enables control of liquid flow through the first orifice. In contrast, piston 47 is shown in Fig. 2 of the Berndtsson reference as communicating with cylinder 44 (interpreted by the Examiner as the first mixing chamber of the claims). The prior art as secondarily relied upon by the Examiner does not overcome this deficiency of the primarily relied upon Berndtsson reference. Moreover, in the Berndtsson reference, the flow is reversed a number of times, resulting in complex flow/operation and design. Accordingly, Applicants respectfully submit that claim 49 distinguishes over and would not have been obvious in view of the relied upon prior art for at least these reasons.

Claim 50 includes in combination that the cartridge comprises a pressure channel "leading from the first mixing chamber and communicating with a connection port in the cartridge, the connection port being adapted for coupling to a pressure source through a connection port of a docking station such that liquid flow through the cartridge is controlled by pressure applied by the pressure source". A simple and cost efficient cartridge is provided.

As noted above, the Examiner has interpreted cylinder 44 in Fig. 2 of the Berndtsson reference as the first mixing chamber of the claims. However, piston 47 within cylinder 44 in Fig. 2 of the Berndtsson reference controls fluid flow. The piston

47 of the Berndtsson reference is essential for the operation of the device in Berndtsson in order to be able to move liquid from the cylinder 44 to the volume space 61. The Berndtsson reference thus does not include a pressure channel leading to a connection port of a docking station, whereby fluid flow is controlled by a pressure source through the connection port of the docking station. The design and control of fluid flow within the device of the Berndtsson reference is thus more complex than the cartridge of claim 50. The prior art as secondarily relied upon by the Examiner does not overcome this deficiency of the primarily relied upon Berndtsson reference. Accordingly, Applicants respectfully submit that claim 49 distinguishes over and would not have been obvious in view of the relied upon prior art for at least these reasons.

Conclusion

The Examiner is respectfully requested to reconsider and withdraw the corresponding rejections, and to pass the claims of the present application to issue.

In the event that there are any outstanding matters remaining in the present application, please contact Andrew J. Telesz, Jr. (Reg. No. 33,581) at (571) 283-0720 in the Washington, D.C. area, to discuss these matters.

Pursuant to the provisions of 37 C.F.R. 1.17 and 1.136(a), the Applicants hereby petition for an extension of two (2) months to October 11, 2009, for the period in which to file a response to the outstanding Office Action. The required fee of \$490.00 should be charged to Deposit Account No. 50-0238.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment for any additional fees that may be required, or credit any overpayment, to Deposit Account No. 50-0238.

Respectfully submitted,

VOLENTINE & WHITT, P.L.L.C.

A handwritten signature in black ink, appearing to read "Andrew J. Telesz, Jr.", with a stylized flourish at the end.

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Attachment: Dictionary Definitions